JUN 2 8 2000

K001700

Section 5: 510(k) Summary

XPlan 2.1 510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

Submitter of Premarket Notification:
Nancy C. MacDonald
Sr. Regulatory Engineer
Radionics
22 Terry Avenue
Burlington, MA 01803
Telephone: (781) 272-1233
Fax: (781) 238-0645

Establishment Registration Number:
1226072

Performance Standards:
No applicable performance standards have been issued under section 514 of the Food, Drug & Cosmetic Act.

Device Name:
XPlan 2.1

Common Name:
Stereotactic Radiation Treatment Planning System

Classification Name:
X-ray radiation therapy system

Safety Summary:
Radionics' system testing for XPlan 2.1 verifies that the XPlan /KonRad software is robust and ready for clinical use. Furthermore, beta site unit testing was performed at two hospitals which utilized film tests to confirm the behavior of the KonRad optimization and the accuracy of the XPlan dosimetry.

Predicate Device:
Radionics XPlan 2.0, 510(k) #K991237, dated August 30, 1999.

Intended Use:
The intended use for XPlan 2.1 is:

> XPlan 2.1 is a stereotactic LINAC-based radiation treatment planning system. XPlan 2.1 localizes lesions to be treated using CT scans, MR scans, and digitized angiographic film. XPlan 2.1 provides a stereotactic planning system for treatment of tumors at sites such as: cranial, base of skull, head and neck. The conformal stereotactic radiation therapy treatments are delivered over multiple fractions.

Device Description:

The XPlan 2.1 system is a stereotactic radiation treatment planning system. It is a modification of the commercially available XPlan 2.0 stereotactic radiation treatment planning system. The functionality of XPlan 2.1 is identical to that of XPlan 2.0, except for the addition of a new module which provides for the planning of Intensity Modulated Radiation Therapy (IMRT). The module, KonRad, will read planning data from XPlan and generate an optimized fluence map for each beam. Subsequently, it will generate leaf patterns which will be used to deliver the calculated fluences.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2000

Nancy C. MacDonald
Senior Regulatory Engineer
Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803

Re: K001700
XPlan 2.1 Sterotactic RTP System Software
Dated: June 2, 2000
Received: June 5, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Ms. MacDonald:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

ODE Indications for Use Statement

510(k) Number (if known): K001700

Device Name: XPlan 2.1 Stereotactic Radiation Treatment Planning System software

Indications for Use:

XPlan 2.1 software is a stereotactic LINAC-based radiation treatment planning system. XPlan 2.1 localizes lesions to be treated using CT scans, MR scans, and digitized angiographic film. XPlan 2.1 provides a stereotactic planning system for treatment of tumors at sites such as: cranial, base of skull, head and neck. The conformal stereotactic radiation therapy treatments are delivered over multiple fractions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use

(Per 21 CFR § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001700